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The Honorable Joel Schneider
United States District Court for the District of New Jersey
Mitchell H. Cohen Building & U.S. Courthouse
4th & Cooper Streets
Room 1050
Camden, New Jersey 08101

Re: Sciele Pharma, Inc., et al. v. Lupin Ltd., et al., C.A. No. 09-037-RBK-JS

Dear Judge Schneider:

I write on behalf of Plaintiff Shionogi in response to the opening pre-conference discovery dispute letters submitted by Defendants Lupin (D.I. 485) and Mylan (D.I. 483).

I. RESPONSE TO LUPIN

As it has throughout discovery, Lupin continues to resist producing legitimate discovery.

1) This Court rejected Lupin's motion for a protective order at the May 11, 2012 hearing. Yet, Lupin spends eight pages of its June 29th letter, D.I. 485 (*hereinafter* "Lupin Letter") rehashing the same arguments regarding the "highly sensitive" nature of the discovery sought by Shionogi.¹ Just as Lupin previously sought to exempt itself from basic discovery obligations, it

¹ In an email following the Court's May 11 ruling and May 14 order, Lupin asserted without qualification that "the judge did not overrule Lupin's objections regarding confidentiality and sensitivity." Ex. W. Exhibits to this letter begin at Ex. W, which follows the last exhibit to Shionogi's opening letter at D.I. 487.

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now ignores this Court's prior rulings to the contrary. Enough is enough. The Court should once again reject Lupin's argument and order Lupin to produce the requested documents.²

2) Lupin claims that despite its "substantial efforts to resolve" the issues raised by Shionogi's discovery requests, that Shionogi "continues to demand all of the documents requested in its discovery demands." That is wrong. In fact, as shown in Shionogi's June 29th letter to the Court, D.I. 487 (*hereinafter* "Shionogi Letter"), Shionogi substantially narrowed the scope of the discovery sought by each of its requests. That narrowed scope is shown in Exhibit X to this letter, which compares Shionogi's original document requests to the requests as narrowed by Shionogi during the meet and confer process.

3) Lupin asserts that "[s]ince the May 11, 2012 hearing, Lupin has produced highly sensitive sales information to Plaintiffs, including information regarding units sold and net sales." Lupin Letter at 1. In fact, the totality of the "highly sensitive information" produced to Shionogi comprises a single, heavily redacted page, providing only a one-line summary of the units sold and net sales for Lupin's infringing product. Shionogi Letter at Ex. J. Apparently, Lupin believes that this single page—in reality, a single line on that page—comprises all of the information it needs to provide to Shionogi. Lupin is wrong.

4) Lupin claims that it "has agreed to produce a significant amount of information to Shionogi" and that it is "in the process of collecting its forecast documents." Despite the Court's ruling that Lupin must produce documents "promptly," Lupin has yet to produce most of these documents and offers no reasonable explanation as to why it has not done so. *See* Shionogi Letter at 12-14.

5) Lupin wrongly asserts that Shionogi did not accept its offer to produce the single-page spreadsheet in un-redacted form. Shionogi did accept that offer, but stated that it also needed the underlying data to confirm the veracity and accuracy of the information contained in the spreadsheet chart. Surely, Lupin, which spends ten pages of its June 29th letter complaining in minute detail about the alleged lack of completeness of Shionogi's document production, understands the need for full disclosure. Lupin should not be heard to complain about Shionogi's far more comprehensive and timely production, while at the same time seeking to foreclose discovery by Shionogi. Indeed, Lupin's complaints about Shionogi's fulsome document production appear to be an attempt to distract the Court's attention from Lupin's own refusal to provide the most basic discovery, despite this Court's order to the contrary.

6) Lupin complains that Shionogi has produced "only 3,065 pages" since the May 11th hearing. But Shionogi's production stands in sharp contrast to the single, redacted page produced by Lupin since that time concerning damages. Indeed, Lupin's complaints seem

² Because Lupin's legal arguments concerning the sensitivity of its information repeat those it made prior to the May 11th hearing, Shionogi has not addressed those arguments in this letter, but instead, refers to the relevant portions of its submissions prior to the May 11th hearing. *See* D.I. 425-47.

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manufactured to generate some disputes of its own, no matter how minor, to weigh against those raised by Shionogi. This is particularly true since, as Lupin itself acknowledges, “Shionogi has agreed that, if documents exist, it will produce them.” Lupin Letter at 8. Given that agreement, Lupin’s complaints simply are not ripe, and there is no need for the Court to resolve them at this time. And Lupin’s complaints concerning the completeness of Shionogi’s production are certainly ironic, given its own flat refusal to provide similar documents. As just one example, Lupin complains that certain customer agreements produced by Shionogi are missing pages, yet refuses to produce *any* of its own such agreements.

A. *Lupin Makes No New or Compelling Arguments for Withholding “Highly Sensitive Commercial Information”*

Despite this Court’s clear ruling that “there is *no bar* to obtaining what has been characterized [by Lupin] as highly sensitive confidential information,” Ex. A (May 11 Hearing Tr.) at 76:5-7, Lupin spends much of its letter simply rearguing the same issue. Lupin again relies on the rejected proposition that “protective orders do not offer a 100% guarantee to the producing party.” Lupin Letter at 6. Yet again, Lupin fails to explain why this Court’s protective order—which contemplates production of precisely the types of documents Lupin refuses to produce—provides insufficient protection.³ Lupin also continues to wrongly argue that the documents Shionogi seeks are not relevant or necessary to Shionogi’s damages case. Contrary to Lupin’s blanket assertion, Shionogi’s opening letter outlines—request by request, as per the Court’s instruction—the relevance and need for the documents it seeks, as well as Shionogi’s efforts to narrow the requests and target only documents sufficient to show the most relevant information. Shionogi Letter at 6-12.⁴ Notably, Lupin has not provided the same kind of request-by-request analysis, relying instead on broad generalizations and supposition.

Despite the Court’s clear direction that it would not entertain merits-based arguments in resolving discovery disputes, *see* Ex. A at 77:11-14, Lupin continues to oppose discovery by persisting in its argument that its positions on the merits should determine its discovery obligations. But relevance under Federal Rule 26 is far broader than Lupin’s narrow view of the merits. *See Oppenheimer Fund, Inc. v. Sanders*, 437 U.S. 340, 351 (1978) (discovery

³ Moreover, during the several meet-and-confers prior to the parties’ letter briefing, despite requests from Shionogi, Lupin once again failed to offer any suggested changes to the protective order that would address its concerns.

⁴ Lupin asserts that Shionogi has requested documents underlying Lupin’s proposed spreadsheet only to test the spreadsheet’s veracity. Although this is a legitimate basis for discovery, *see Hite v. Peters*, Civil No. 07-4492-RMB-AMD, 2009 U.S. Dist. LEXIS 51894, *4 (D.N.J. 2009) (compelling production of documents that moving party argued were “necessary to verify, corroborate, refute, and/or add to the evidence” previously provided), it is not the only basis. As asserted in Shionogi’s opening letter, these documents contain details such as individualized rebates, discounts, and contract terms that are relevant to both the lost profits and reasonably royalty inquiries.

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encompasses “any matter that bears on, or that reasonably could lead to other matter that could bear on, any issue that is or may be in the case.”). This is *discovery*, not a dispute about which party will prevail on the merits. Shionogi is entitled to seek discovery relevant to its theory of the case, regardless of whether Lupin agrees with that theory. See *Thiokol Corp. v. Alliant Techsystems, Inc.*, C.A. No. 95-706, D.I. 63, slip op. at 9 (D. Del. Nov. 13, 1996) (granting discovery where requesting party “has explained how it intends to implement this information”) (attached hereto as Ex. BB).

As just one example, Lupin persists in arguing that it need not produce *any* discovery relevant to price erosion because, in its own estimation, Shionogi has not lowered prices. Lupin Letter at 4 n. 1. As explained in Shionogi’s opening letter, Lupin is wrong. Lupin’s infringement, resulting in the introduction of Watson’s *lower priced* authorized generic, has caused the price of patented product being sold by Plaintiffs to erode. See Shionogi Letter at 8. In any event, whether Lupin agrees is beside the point: Shionogi is entitled to seek discovery going to **Shionogi’s** theory of price erosion, whether or not Lupin believes that theory is correct.

Similarly, Lupin argues that its costs and profits are irrelevant to Shionogi’s lost profits damages claim. Lupin Letter at 7. But as Shionogi explained in detail in its opening brief, Lupin’s sales, cost data, marketing information, and agreements and communications with customers are directly relevant to two of the *Panduit* factors that dictate the lost profit analysis—that is, demand for the patented product and presence or absence of non-infringing substitutes. Shionogi Letter at 3. And, once again, whether or not Lupin agrees with this proposition should not dictate whether Shionogi is entitled to this clearly relevant discovery.

In its letter, Lupin relies on a single case in support of its position that the requested costs and profits discovery is not relevant to Shionogi’s lost profits damages claim. See Lupin Letter at 7 (citing *Whelan v. A. Ward. Enters., Inc.*, C.A. No. 01-2874, 2002 WL 1745614, at *3 (E.D. Pa. Jul. 23, 2002)). There, the court “examined the Defendants’ [infringers] sales records” to determine the amount of profits the plaintiffs would have made but for defendants’ infringement, and used the “Defendants’ records” to determine the lost profit award. *Id.* Thus, even Lupin’s own authority leads to the conclusion that its costs and profits information is relevant and accordingly, should be produced.

Lupin also asserts that “Lupin’s costs and profits are . . . not needed for a reasonable royalty analysis” because “[t]he primary inquiry . . . is to assess what the parties would have agreed at the moment before the alleged infringement commenced” and “[t]his determination is not based on the alleged infringer’s actual profits or profit margin.” Lupin Letter at 7. Lupin’s position does not square with the multi-point *Georgia-Pacific* analysis. See *Radio Steel & Mfg. Co. v. MTD Products, Inc.*, 788 F.2d 1554, 1557 (Fed. Cir. 1986) (approving district court’s royalty analysis because infringer “expected to make a net profit of about six percent on its sale of infringing wheelbarrows.”). Lupin also does not, and cannot, explain how a jury could conduct a reasonable royalty damages calculation without knowing an infringer’s actual profits. More specifically, if the amount of damages to be paid as a reasonable royalty is 70% of net sales, *i.e.*,

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gross sales minus costs, a jury must know what those net sales are, which clearly first requires discovery of the infringer's sales and profit numbers.

Contrary to Lupin's arguments that its actual profits are not relevant to determining a reasonable royalty, in fact, Federal Circuit precedent "supports the proposition that an actual infringer's profit margin can be relevant to the determination of a royalty rate in a hypothetical negotiation." *Interactive Pictures Corp. v. Infinite Pictures, Inc.*, 274 F.3d 1371, 1385 (Fed. Cir. 2001). And directly contrary to Lupin's argument that its actual profit margin is not relevant, in *State Indus., Inc. v. Mor-Flo Indus. Inc.*, 883 F.2d 1573 (Fed. Cir. 1989), the court cited to the infringer's actual gross and net profits in determining the appropriateness of the district court's reasonable royalty determination. 883 F.2d at 1580-81 ("Mor-Flo's gross profit during the preceding seventeen months was 19.6% with a net incremental profit of 17.48%. Finally, during the period of infringement, Mor-Flo's net profits varied from 5.9% to 7.3%. In light of all this, it seems to us the district court could very well conclude that a royalty of 3% of Mor-Flo's net sales is reasonable.").

In sum, the relevance and necessity of the challenged documents, as outlined in Shionogi's opening letter, far outweigh Lupin's already rejected concerns over sensitivity, which are adequately addressed by the protective order and belied by both parties' productions of other, similar information to date. *See Sega Enters. v. Accolade, Inc.*, No. 92-15655, 1993 U.S. App. LEXIS 78, *67-69 (9th Cir. 1993) (appropriate remedy for concern over trade secrets is a protective order that "restrict[s] access to the disputed material to the opposing party's counsel" and "independent experts") (citing *Micro Motion*).⁵ Further, Shionogi has significantly narrowed its requests to target a low volume of readily accessible information. Accordingly, Shionogi requests that this Court order Lupin to produce, at long last, all of the documents called for by Shionogi's narrowed requests within ten days of the July 13th hearing.

B. Lupin's Production and its Proposed Spreadsheet are Inadequate

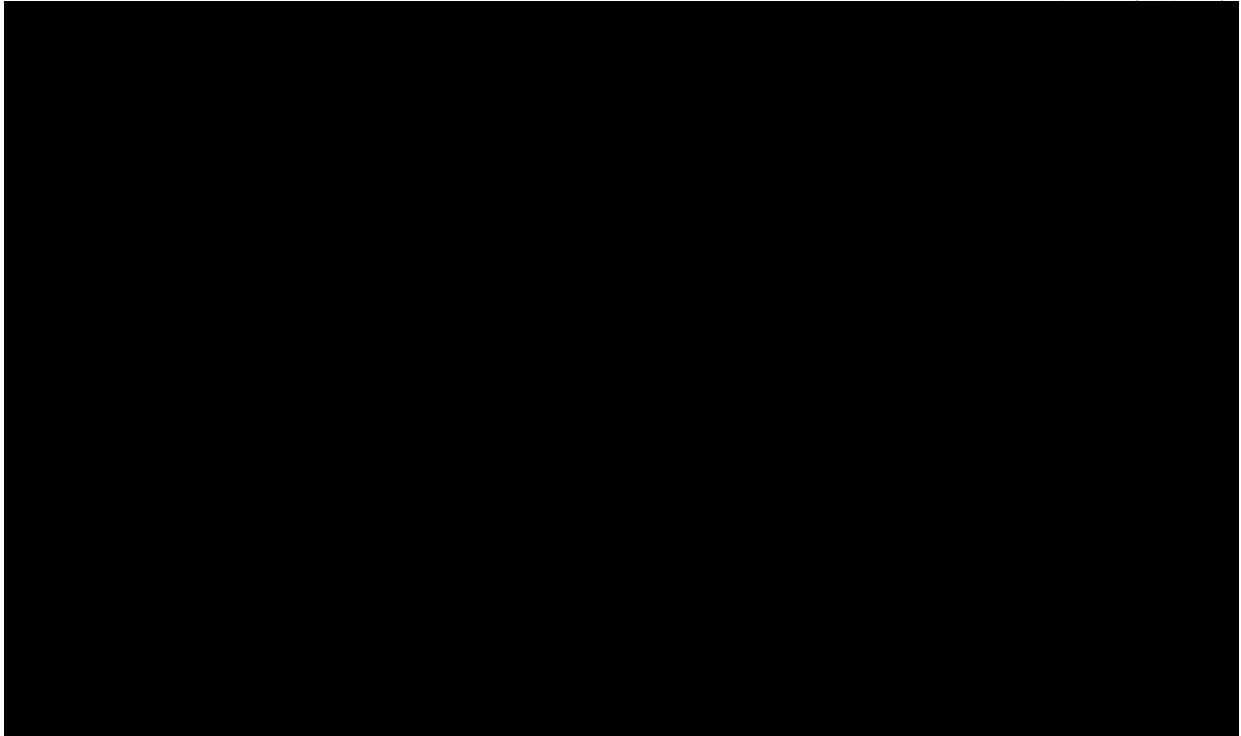
Lupin asserts that "[s]ince the May 11, 2012 hearing, Lupin has produced highly sensitive sales information to Plaintiffs, including information regarding units sold and net sales." To be clear, the entirety of Lupin's production is reproduced below:

⁵ Shionogi notes that both *Micro Motion* and *Mannington Mills* concern discovery requests to third parties, not litigants. Moreover, in *Micro Motion*, "[d]iscovery on damages was completed" and *Micro Motion* sought duplicative, burdensome third party discovery to "update its damages evidence" and to attempt to introduce new theories in a second trial. 894 F.2d 1318, 1323-24. In *Mannington Mills*, *Mannington* was unable to establish the need for third party discovery because it "presumably has access or will have access to similar information from its opponents" 206 F.R.D. 525, 531. In this case, Shionogi's opponent, Lupin, has attempted at every turn to foreclose damages discovery.

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Lupin's proposed summary spreadsheet would be nothing more than the un-redacted version of this page, Lupin Letter at 8, ostensibly revealing the individual customers and information that make up the figures on the bottom line. Lupin asserts that by removing these redactions, it would provide all necessary discovery for the rest of the case.

As explained in Shionogi's opening letter, even in un-redacted form, this spreadsheet necessarily lacks customer-level detail, including unique terms of purchase, rebates, discounts, and returns. It provides no information that itself may lead to the discovery of admissible evidence or identify potential witnesses with knowledge of the underlying information. Shionogi also requires such underlying documents to verify the information in the spreadsheet itself. Lupin has demanded precisely these documents from Shionogi, and Shionogi has produced them without complaint.

Moreover, the spreadsheet does not contain Lupin's communications with third parties, nor the detail underlying the profitability of the product. Finally, Lupin's claim that Shionogi can simply depose a single Lupin witness, who will verify and provide context to the spreadsheet, is no answer. Lupin Letter at 6. Even if Shionogi agreed that Mr. Hoffman is the sole Lupin witness with knowledge on this subject, Shionogi is entitled to the underlying information with which to depose him.

1. Lupin's work product argument is inappropriate

In another attempt to block legitimate discovery, Lupin now threatens that if this Court orders production of any documents underlying the proposed spreadsheet, Lupin will claim work

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product over the spreadsheet itself. Lupin Letter at 8. Lupin's use of work product as a bargaining chip is inappropriate.

First, Lupin has an independent, continuing obligation to respond to Shionogi's Expedited Interrogatory Nos. 1 and 2, which request precisely the information contained in the proposed spreadsheet. Whether Lupin provides the requested information by responding to those interrogatories or through the simple act of producing a spreadsheet it has already created, it must produce that information.

Lupin's position also turns the notion of discovery compromise on its head—under Lupin's view, many compromises reached by opposing parties regarding the scope of discovery could result in further withholding under the work product doctrine. Certainly that is not what this Court intended when it instructed the parties to work together to narrow disputes and move forward.

Finally, documents do not arbitrarily gain and lose work product status based on a party's disagreement with this Court's rulings—tellingly, Lupin said nothing about work product when it first offered the spreadsheet, nor at any point prior to its letter. Moreover, any work product objection would be unfounded because the facts contained therein presumably are kept in the ordinary course of Lupin's business. Lupin cannot shield them by putting them in a single document and calling it “work product.”

2. Lupin still has not produced promised documents

Finally, although Lupin asserts for the first time in its letter that it will finally produce forecast documents by July 9th, Lupin has still not produced the following categories of documents, all of which it agreed to produce during the May 24 meet-and-confer:

1. internal Lupin communications regarding the importation and sale of its ANDA product (Document Request No. 33);
2. documents regarding the importation into the United States of Lupin's ANDA product (Document Request No. 34);
3. batch records for the manufacture of Lupin's ANDA product (Document Request No. 38);⁶ and

⁶ On July 5, 2012, Shionogi received a production which Lupin described as “batch records relating to drugs sold during the launches in September 2011 and April 2012.” *See* Ex. Y (email from Lupin to Shionogi, dated July 5, 2012). Given the timing of Lupin's production vis-à-vis this letter, Shionogi will review the documents and reserves its right to object to the production if necessary.

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4. documents related to [REDACTED], including documents within the possession of [REDACTED] (Document Request Nos. 57-63).

Although Lupin has repeatedly promised the production of these documents in previous correspondence, it entirely omits them from its June 29th letter. Accordingly, Shionogi requests that this Court order Lupin to produce all remaining documents within ten days of the hearing.

C. Shionogi is Addressing Lupin's Alleged Deficiencies, Which Lupin Knew Before Submitting its Letter to the Court

Pages 8-14 of Lupin's letter allege a laundry list of deficiencies in Shionogi's document production. Shionogi has told Lupin repeatedly that it is working diligently to address these issues. Shionogi has also repeatedly told Lupin in no uncertain terms that it is not "withholding" any otherwise discoverable documents. Lupin Letter at 8. Shionogi has produced, and will continue to produce, the documents identified by Lupin, if and when they are located pursuant to a reasonable and diligent search.⁷ Indeed, Lupin acknowledges that "Shionogi has agreed that, if documents exist, it will produce them." Lupin Letter at 8. Given that agreement, Lupin's complaints regarding Shionogi's document production are not ripe for any resolution by the Court. Instead they appear designed to detract from Lupin's own deficiencies.

Lupin also complains that "at least two" of Shionogi's interrogatory responses require supplementation. This dispute is also not ripe. Shionogi has informed Lupin that it understands its obligations under the Federal Rules to supplement interrogatories that are "incomplete or incorrect." Although Shionogi has determined that no responses require supplementation at this time, Shionogi will supplement any responses that require supplementation before the end of fact discovery.

II. RESPONSE TO MYLAN

Mylan has not raised any issues regarding Shionogi's production of documents or written discovery responses. Mylan merely raises a single issue regarding the production of Shionogi's witnesses, but states that it is not seeking relief from the Court at this time. Shionogi agrees that there is no issue here that requires the Court's attention.

⁷ Shionogi also notes that, since the May 11th hearing, Lupin has apparently parsed through Shionogi's entire production searching for alleged deficiencies—many of which concern documents produced in May 2011 but which Lupin raised for the first time more than a year later in June 2012. At the same time, it has produced only a single page of its own documents and failed to produce forecasts and other documents that it agreed to produce at the May 11th hearing and that the Court ordered "promptly" be produced on May 31st. Lupin's assertions of burden associated with its own document collection are belied by its extensive effort to raise every issue, no matter how minor, with Shionogi's production to date.

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Shionogi fully intends to produce witnesses in accordance with its objections and responses to Mylan's 30(b)(6) notice. As the designated witnesses will testify regarding 30(b)(6) topics from both Lupin and Mylan, Shionogi will produce each witness only once in response to both defendants' notices. Because the likely designees will cover topics which are related to the discovery disputes between Shionogi and Lupin, Shionogi plans to designate and produce its witnesses after the outstanding discovery disputes with Lupin have been resolved.

III. THE [REDACTED]

On June 27, 2012, Lupin informed Shionogi that it anticipated producing [REDACTED] on July 3, 2012. *See* Ex. I (email from Lupin to Shionogi, dated June 27, 2012). Lupin also asserted that Shionogi's request for documents related to [REDACTED]

[REDACTED] *Id.* Shionogi's response to Lupin's position is contained in Shionogi's June 29th letter. Shionogi Letter at 9.

On the evening of June 29th, after Shionogi had finalized its opening letter, Lupin informed Shionogi that [REDACTED] and for that reason, Lupin rescinded its offer to produce any documents. *See* Ex. Z (email from Lupin to Shionogi, dated June 29, 2012). [REDACTED]

[REDACTED] *See* Ex. AA (Mylan's Responses and Objections to Shionogi's Third Set of Requests for the Production of Documents and Things).

On July 3, 2012, Shionogi asked Mylan to provide a written justification for its objection to Lupin's production by 12:00 p.m. today. No response was forthcoming.

Shionogi is entitled to production from both Lupin and Mylan [REDACTED], as well as [REDACTED]

[REDACTED] As explained in Shionogi's June 29th letter, these documents are relevant to both lost profits and the reasonable royalty calculation, as they indicate the demand for and value placed upon Lupin's ANDA, and therefore its ANDA product.

IV. CONCLUSION

Shionogi respectfully requests that the Court order both Lupin and Mylan to produce, within 10 days of the July 13th hearing, all of the documents and information described in Shionogi's June 29th letter and this letter. Shionogi further requests that the Court grant Shionogi fees and costs and other relief necessary in light of Lupin's repeated failure to obey court orders and produce legitimate discovery.

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Respectfully submitted,

/s/ Karen Jacobs Louden

Karen Jacobs Louden (#2881)

KJL/jy

Enclosures

cc: All Counsel of Record
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